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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,749	03/15/2004	Barry N. Kreiswirth	19124.0016	8023
23517 7590 04/09/2007 BINGHAM MCCUTCHEN LLP 2020 K Street, N.W. Intellectual Property Department WASHINGTON, DC 20006			EXAMINER SKIBINSKY, ANNA	
			ART UNIT 1631	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE 3 MONTHS		MAIL DATE 04/09/2007		DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/799,749	Applicant(s) KREISWIRTH ET AL.	
	Examiner Anna Skibinsky	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 51-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/15/04; 5/17/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Election/Restriction

1. Applicant's election with traverse of Group I and SEQ ID NO: 55 in the reply filed on 1/04/07 is acknowledged. The traversal is on the ground(s) that the novelty of the claimed invention of claim 51 is not based on the particular nucleotide sequence. This is not found persuasive because claim 51 remains generic and is treated as such while the plurality of sequences in the dependent claims (54 and 61) are examined to the extent of the elected claims and sequences.
2. The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 51-63 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 51-63 are drawn to a method for identifying a subspecies of *Staphylococcus aureus*. The method involves the application of algorithms and computations that results in a determination of phylogenetic relatedness and, therefore, involves the application of a judicial exception. Regarding inventions involving the application of a judicial exception, said application must be a practical application of the

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judicial exception that includes either a step of a physical transformation, or produces a useful, concrete, and tangible result (State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998), AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999))). In the instant claims, there is no step of physical transformation that results from said application of a judicial exception thus the Examiner must determine if the instant claims include a useful, concrete, and tangible result.

In determining if the claimed subject matter produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, and substantial. For a claim to be "concrete," the process must have a result that is reproducible. For a claim to be "tangible," the process must produce a real world result. Furthermore, the claim must be limited only to statutory embodiments.

Claims 51-63 do not produce a tangible result. A tangible result requires that the claim must set forth a practical application to produce a real-world result. This rejection could be overcome by amendment of the claims to recite that a result of the method is outputted to a display, a user, a readily accessible memory or other computer on a network, or by including a physical transformation.

Claim Rejections - 35 USC § 112-2nd paragraph

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 51-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 51 recites a database with "at least one *Staphylococcus aureus* sequence region" (in lines 6-7) where the said sequence region further comprises a forward primer upstream of the sequence and a reverse primer down stream of the sequence (lines 10-12). This causes the metes and bounds of the claims to be vague and indefinite because it is unclear if the *Staphylococcus aureus* sequence region initially recited in claim 51, lines 6-7, includes the recited two primer regions or if the two primer regions fall outside (i.e. beyond) the recited *Staphylococcus aureus* sequence region and are therefore not included in the *Staphylococcus aureus* sequence, wherein the "at least one *Staphylococcus aureus* sequence region" plus two primer regions make up a separate sequence. For the purpose of examination, the "at least one *Staphylococcus aureus* sequence region" has been construed to include the two primer regions.

4. Claims 55-57 recite limitations of claim 54. Claim 54 is drawn to the region of variable number of tandem repeats that comprises SEQ ID NO: 55. It is unclear if claims 55-57 intend to define a different sequence other than SEQ ID NO: 55, or if claims 55-57 further limit the SEQ ID NO: 55. For the purpose of examination, the limitations of claims 55-57 has been construed as describing the characteristics of SEQ ID NO: 55 and are reciting features of SEQ ID NO:55.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 51-63 are rejected under 35 U.S.C. 103(a) as being unpatentable by Hoe et al. (1990) in view of Genbank accession number AJ224764.

8. The instant claims recite obtaining a sample of microorganisms, sequencing a first region of a nucleic acid, comparing the region with sequence data stored in a database comprising at least one *Staphylococcus aureus* sequence region and determining a measure of phylogenetic relatedness between the microorganism sample and a plurality of samples in the database, where in the *Staphylococcus aureus* sequence region further comprises a forward primer upstream of the sequence and a

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reverse primer downstream of the sequence and the primers permit identification of a region of variable tandem repeats.

9. Hoe et al. teach obtaining pathogenic microbial species, analyzing sequences of *Streptococcus* with electrophoresis (Abstract and page 254, col. 1, lines 1-20) and comparing of sequences to those in the Genbank database (page 255, Figure 1).

Samples of streptococcus strains are collected from patients, cultured and analyzed for their molecular origins (i.e. phylogenetic relatedness), as required by claim 51, lines 1-9. Further, the Genbank database contains at least one *Staphylococcus aureus* sequence region, in particular SEQ ID NO: 54 (accession number AJ224764), as required by claim 62.

10. Hoe et al. also teach performing PCR to identity polymorphic regions in the streptococci (page 258, col. 1, lines 1-10), which inherently requires the use of primers, as required in claim 51, lines 10-13. Genbank contains a plurality of Streptococci sequences and primers that are conducive of permitting the identification of a region along the Staphylococcus region, such as the one claimed, which has tandem repeats.

11. Hoe et al. teach a method of searching the Genbank database for Streptococci sequences but do not specifically teach a database containing a *Staphylococcus aureus* sequence, namely SEQ ID NO: 54. However, a search in Genbank discloses SEQ ID NO: 54, from *Staphylococcus aureus*.

12. Claim 52 recites a limitation characterizing the sequence in the database of claim 51, namely that said sequence has a mutation rate sufficient to differentiate between subspecies of *Staphylococcus aureus*.

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13. SEQ ID NO: 54 was identified in the Genbank database (accession number AJ224764).

14. Claim 53 and 54 recite that the sequence comprises tandem repeats, namely those of SEQ ID NO: 55 and claim 63 recites that the region of variable number of tandem repeats is sufficient to determine the phylogenetic relatedness between microorganisms as recited in claim 51.

15. SEQ ID NO: 54 was identified in the Genbank database comprises tandem repeat regions of SEQ ID NO: 55, for example at nucleic acids 187 through 204 and 259 through 276. The specification of the instant application recites that SEQ ID NO: 55 allows for the identification of phylogenetic relatedness of organisms (page 47, lines 4-7).

16. Claims 55-57 and 60-61 recite the characteristics of SEQ ID NO: 55.

17. SEQ ID NO: 54 was identified in the Genbank database, which begins with codon GAT and comprises SEQ ID NO: 55. The instant specification (page 46, lines 7-20) recites that SEQ ID NO: 55 sequence begins with codon GAT and may comprise at least one point mutation which are stable enough for the identification of sequences containing the repeats, and thus reads on the limitations of claims 55-57 and 60-61.

18. Claims 58 and 59 recites a forward primer of SEQ ID NO: 75 and SEQ ID NO: 76 and reverse primer of SEQ ID NO: 76 and SEQ ID NO: 77.

19. SEQ ID NO: 54 was identified in the Genbank database and the instant specification recites (page 45, lines 5-18) that said sequence includes forward primer of SEQ ID NO: 76 and reverse primer of SEQ ID NO: 77, as shown in Figure 10A in the

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instant application. Further, Figure 10B shows a breakdown of SEQ ID NO: 54 where it is shown to include SEQ ID NO: 75 as well.

20. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used the Genbank sequence data of *Staphylococcus aureus* as contained in Genbank, accession number AJ224764, with the method of comparing Streptococci sequences taught by Hoe et al. One of skill in the art would have been motivated to use the Genbank database containing accession number AJ224764 which is a sequence belonging to *Staphylococcus aureus* because Hoe et al. teach a search for sequences of illness causing bacteria strains, namely, Streptococci sequences using Genbank in their analysis of the evolutionary lineages of group A *Streptococcus* (Abstract and Figure 1). Furthermore, the art of Hoe et al. differs from the instantly claimed invention by the specific sequences disclosed in the database, which is nonfunctional descriptive material. Hoe et al. teaches Streptococci sequences while the instant claims recite a sequence of *Staphylococcus aureus*, thus the method of prior art and instant claims differ in the type of sequence data used to perform the method. Since the data is nonfunctional descriptive material, it is not given patentable weight. Therefore, the invention as a whole would have been prima facie obvious, absent evidence to the contrary.

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

22. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

23. Claims 51-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoe et al.

24. The instant claims recite obtaining a sample of microorganisms, sequencing a first region of a nucleic acid, comparing the region with sequence data stored in a database comprising at least one *Staphylococcus aureus* sequence region and determining a measure of phylogenetic relatedness between the microorganism sample and a plurality of samples in the database, where in the *Staphylococcus aureus* sequence region further comprises a forward primer upstream of the sequence and a reverse primer downstream of the sequence and the primers permit identification of a region of variable tandem repeats.

25. The method of claim 51 is recited in lines 1-5 and 6-9 while claim 51, lines 6 and 10-13 characterize the sequence data used in the claimed method. The method as

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instantly claimed differs from method of Hoe et al. only in the content of the sequence data used in the search. The sequence used in the database search of instant claims 51-63 is data which is nonfunctional descriptive material and not given patentable weight. The MPEP states in 2106.01:

When nonfunctional descriptive material is recorded on some computer-readable medium, in a computer or on an electromagnetic carrier signal, it is not statutory and should be rejected under 35 U.S.C. 101. In addition, USPTO personnel should inquire whether there should be a rejection under 35 U.S.C. 102 or 103. USPTO personnel should determine whether the claimed nonfunctional descriptive material be given patentable weight. USPTO personnel must consider all claim limitations when determining patentability of an invention over the prior art. In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 403-04 (Fed. Cir. 1983). USPTO personnel may not disregard claim limitations comprised of printed matter. See Gulack, 703 F.2d at 1384, 217 USPQ at 403; see also Diehr, 450 U.S. at 191, 209 USPQ at 10. However, USPTO personnel need not give patentable weight to printed matter absent a new and unobvious functional relationship between the printed matter and the substrate. See In re Lowry, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994); In re Ngai, 367 F.3d 1336, 70 USPQ2d 1862 (Fed. Cir. 2004).

The above paragraph cites four court decisions which, when taken together, give the same message and theme regarding prior art and patentability of computerized media.

In *In re Gulack*, the CAFC ruled to give the appellant's claims patentability over the prior art because the mathematical educating device served as functional descriptive material, distinguishing it over the prior art.

As stated on page 1 of the decision:

Printed matter that is not functionally related to substrate does not distinguish invention from prior art in terms of patentability; although printed matter must be considered, in that situation it may not be entitled to patentable weight.

In *In re Ngai*, the CAFC did not give patentable weight over the prior art to an identical process of amplifying ribonucleic acids with a distinct set of printed instructions

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to execute this process because this set of instructions is not functional and therefore does not serve to distinguish it over the prior art.

In *In re Lowry*, the CAFC gives functional data structures patentability, and distinguishes these data structures and computer memory from nonfunctional printed matter.

As stated on page 1 of the decision:

Claims for data processing system are neither anticipated by, nor obvious in view of, prior patent for database management system, since claimed invention, which employs plurality of attribute data objects having both hierarchical and non-hierarchical relationships, involves organization of information and its interrelationships which reference neither discloses nor suggests.

In *Diehr*, the US Supreme Court ruled analogously to the previous three cases with regards to mathematical equations. As stated at the bottom of page 10 of the ruling:

when a claim containing a mathematical formula implements or applies that formula in a structure or process which, when considered as a whole, is performing a function which the patent laws were designed to protect (e.g., transforming or reducing an article to a different state or thing), then the claim satisfied the requirements of 35 U.S.C. 101.

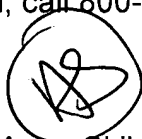
The difference between Hoe et al. and the claimed invention constitutes non-functional descriptive material because the content of the *Staphylococcus aureus* sequence data does not alter how the instantly claimed method functions. Therefore, no patentable weight is given to the content of the database in the method of using said data.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anna Skibinsky whose telephone number is (571) 272-4373. The examiner can normally be reached on 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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